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| APPLICATION NO. 097027,089 | FILING DATE 02/02/99 | PROPRIETOR PORTUGAL | FIRST NAMED INVENTOR F | ATTORNEY DOCKET NO. |
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HM12/0907

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SQUAY EXAMINER

ABE UNIT

PAPER NUMBER

09/07/99 6

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/027,089

Applicant(s)

Dornburg

Examiner
Jehanne Souaya

Group Art Unit
1655



☒ Responsive to communication(s) filed on Feb 20, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-7 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Specification

1. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(1). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.
2. This application is informal in the arrangement of the specification. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 1. Field of the Invention.
 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.

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- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

Indefinite

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-5 are indefinite in the recitation of “discriminating” in line 1 of claim 1 as it is unclear what is encompassed by the term. For example, does the term mean to distinguish the identity of one or more taxonomic groups, or is it meant to simply identify the presence of one or more taxonomic groups in a sample.

B. Claims 1-5 are indefinite in the recitation of “subsequences” because it is unclear from the claim language what a “subsequence” of an operon is. The specification does not define

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this term, therefore, it is unclear whether a "subsequence" is any nucleotide sequence of an operon, or if it refers to a specific region of an operon.

C. Claim 1 recites the limitation "each oligonucleotide" in line 3. There is insufficient antecedent basis for this limitation in the claim as it is unclear what oligonucleotide is referred to.

D. Claims 1-5 are indefinite in the recitation of "operon subsequence reactivity" as this term is not defined in the specification nor is it an art excepted phrase. Does the reactivity of the operon refer to its function in gene expression, or to hybridization with a probe?

E. Claims 1-5 are indefinite in the recitation of "two or more temperatures relative to the probe's calculated..." as it is unclear from the recitation what the metes and bounds of the term "relative" are. For example, does the term refer to temperatures above or below the probes T_m . Furthermore, it cannot be determined from the recitation in the claim what temperatures are encompassed by the term "relative". Can these temperatures differ by 1 degree, 10 degrees, 15 degrees, etc.

F. Claims 1-5 are indefinite because the claims fail to include a positive process step relating back to the preamble. In claim 1, the preamble states "a method for discriminating among members..." but the final process step is "assaying for hybridization of the probes to the samples in order to determine the relative level of reactivity..". Therefore the method is unclear as to whether it is to discriminate among members of taxonomic groups or to determine the relative level of reactivity of operon subsequences.

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G. Claims 2-7 are indefinite in the recitation of "probe SEQ ID NO..." because it is unclear what probe is referred to in the method claim. Applicant can easily overcome this rejection by reciting instead "the probe of SEQ ID NO..."

H. Claim 6 is in improper Markush form. (See MPEP 2273.05 (h)). A markush group can either read "selected from A, B, or C" or alternatively "selected from the group consisting of A, B, and C". Appropriate correction is required. Applicant can easily overcome this rejection by reciting : --RNA sequences selected from the group consisting of SEQ ID NOS 1, 2, 3, and 4--; or --RNA sequences selected from SEQ ID NOS 1, 2,3, or 4--.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Cilia et al. (Mol Biol. Evol. Vol. 13, pp 451-461; 1996).

Claim 7 is drawn to any variant through the addition, subtraction, or modification of bases of SEQ ID NOS 1-4. Accordingly, claim 7 is anticipated by Cilia et al which teaches the variants of SEQ ID NOS 1, 2, and 4, (see FIG 3, and table 1), as well as most of the sequence of SEQ ID

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NO 4(see FIG 3, 1st row). Enclosed is the results of a sequence search, which also discloses variants of SEQ ID NO 2, and the complete nucleotide sequence of SEQ ID NOS 1 and 4. This sequence search cites Cilia et al, identified above, as disclosing the accession numbers for these results (see table 1 of Cilia et al).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kohne et al (US Patent 5,601,984).

Kohne teaches a method for detecting the presence or amount of a taxonomic group of organisms (see abstract). Kohne teaches that the method comprises contacting the nucleic acid of the organisms whose presence, identification, and quantitation can be determined, with a marked probe comprising nucleic acid molecules complementary to RNA or other nucleic acid sequences, under nucleic acid hybridization conditions, and determining the degree of hybridization (level of reactivity) that has occurred (abstract). Kohne teaches that the lack of conservation in DNA

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sequences of many RNAs allows the production of probes which can readily distinguish between closely related organisms or viruses (see col. 6, lines 9-12). Kohne teaches that the method thus relates to specifically and sensitively detecting and quantitating any organism containing R-RNA (col. 1, lines 25-35). Kohne teaches that the probe is single stranded whose length can vary from 5 bases to tens of thousands of bases (col. 6, lines 32-40). Kohne teaches that the probe should be complementary to the sequences to be detected, but does not have to hybridize perfectly to the target sequence (col 6, lines 40-45). Kohne further teaches that the mixture of probe and target must be incubated at a specific temperature for a long enough time such that hybridization can occur. Although Kohne does not teach "testing samples ... under controlled stringency conditions at two or more temperatures...", it was readily known in the art at the time of the invention that hybridization of a probe to a target is influenced by the temperature at which the hybridization reaction occurs. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kohne to include a step to test the samples at two or more temperatures. The ordinary artisan would have been motivated to modify the method of Kohne to determine the temperatures at which a probe will most specifically bind to a target.

10. Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kohne as applied to claim 1 above, and further in view of Cilia et al.

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Kohne teaches a method for detecting the presence or amount of a taxonomic group of organisms (see abstract). Kohne teaches that the method comprises contacting the nucleic acid of the organisms whose presence, identification, and quantitation can be determined, with a marked probe comprising nucleic acid molecules complementary to RNA or other nucleic acid sequences, under nucleic acid hybridization conditions, and determining the degree of hybridization (level of reactivity) that has occurred (abstract). Kohne teaches that the lack of conservation in DNA sequences of many RNAs allows the production of probes which can readily distinguish between closely related organisms or viruses (see col. 6, lines 9-12). Kohne teaches that the method thus relates to specifically and sensitively detecting and quantitating any organism containing R-RNA (col. 1, lines 25-35). Although Kohne does not teach the method using the probes sequences claimed in the instant application, Cilia teaches the nucleotide sequences of these probes as well as the use of the relevant regions of E. Coli, Shigella, and Salmonella, to construct phylogentic trees in order to analyze similar taxonomic groups of bacteria (see abstract, table 1, fig 1-3). Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the nucleotide sequences disclosed in Cilia, as well as the already known sequences of E. Coli, Shigella, and Salmonella strains, in the method of Kohne for the purposes of detecting taxonomic groups of organisms in a sample.

Although neither Kohne nor Cilia teach RNA molecules of the nucleotide sequences of SEQ ID NOS 1-4, Kohne teaches that the probe can be either DNA or RNA (col. 6, line 48), and Cilia teaches the deoxyribonucleotide sequences of SEQ ID NOS 1, 2, and 4. Therefore it would

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have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct probes of SEQ ID NOS 1, 2, and 4 which could hybridize to RNA as well as DNA.

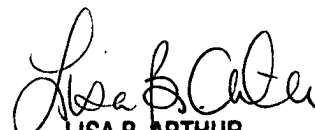
11. No claims are allowable over the prior art.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jehanne Souaya
Patent examiner
august 25, 1999


LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800-1600